

In re Application of: Michal DANIELY et al
Serial No.:10/771,440
Filed: February 5, 2004
Office Action Mailing Date: March 20, 2008

Examiner: Duffy, Bradley
Group Art Unit: 1643
Attorney Docket: 26003

In the Claims:

1-36. (Canceled)

37. (Currently amended) A method of identifying transitional cell carcinoma cells in a urine sample comprising:

(a) staining nucleated cells of the urine sample by using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou or and Hematoxylin-Eosin to thereby obtain stained nucleated cells; so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma, and;

(b) staining said stained nucleated cells resultant of step (a) by using fluorescent *in situ* hybridization (FISH) so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell, and;

(c) imaging said stained nucleated cells resultant of steps (a) and (b) so as to obtain images of said stained nucleated cells, and;

(d) identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality, wherein presence of said morphological abnormality and said chromosomal abnormality in said single cell is indicative of a presence of a cancerous cell;

to thereby identifying the transitional cell carcinoma cells in the urine sample.

38. (Canceled)

39. (Original) The method of claim 37, wherein the transitional cell carcinoma cells are associated with bladder cancer and/or kidney cancer.

40. (Original) The method of claim 37, wherein the urine sample is obtained via voided urine or catheterization.

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41-53. (Canceled)

54. (Previously Presented) The method of claim 37, wherein step (c) is effected using an automated cell imaging device capable of at least dual imaging.

55. (Currently amended) A method of diagnosing bladder cancer in a subject, the method comprising:

- (a) obtaining a urine sample from the subject;
- (b) staining nucleated cells of said urine sample by using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou or and Hematoxylin-Eosin to thereby obtain stained nucleated cells, so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma, and;
- (c) staining said stained nucleated cells resultant of step (b) by using fluorescent in situ hybridization (FISH), so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell and;
- (d) imaging said stained nucleated cells resultant of steps (b) and (c) so as to obtain images of said stained nucleated cells, and;
- (e) identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality, wherein presence of said morphological abnormality and said chromosomal abnormality in said single cell is indicative of a presence of a cancerous cell,
to thereby determine the presence or absence of cancerous cells within said stained nucleated cells, wherein said presence of said cancerous cells is indicative of a positive cancer diagnosis.

56. (Canceled)

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57. (Original) The method of claim 55, wherein the urine sample is obtained via voided urine or catheterization.

58-71. (Cancelled)

72. (Currently amended) A method of identifying transitional cell carcinoma cells in a urine sample comprising:

- (a) staining nucleated cells of the urine sample by using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou or and Hematoxylin-Eosin to thereby obtain stained nucleated cells, so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma and subsequently
- (b) imaging said stained nucleated cells resultant of step (a) so as to obtain images of said stained nucleated cells; and subsequently
- (c) staining said stained nucleated cells resultant of step (a) by using fluorescent in situ hybridization (FISH) to thereby obtain stained nucleated cells so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell; and subsequently
- (d) imaging said stained nucleated cells resultant of step (c) so as to obtain images of said stained nucleated cells; and subsequently
- (e) simultaneously viewing said images stained nucleated cells resultant of steps (ab) and (ed), and;
- (f) identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality, wherein presence of said morphological abnormality and said chromosomal abnormality in said single cell is indicative of a presence of a cancerous cell
to thereby identifying the transitional cell carcinoma cells in the urine sample.

73. (Currently amended) A method of diagnosing bladder cancer in a subject, the method comprising:

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- (a) obtaining a urine sample from the subject;
- (b) staining nucleated cells of said urine sample by using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolau or and Hematoxylin-Eosin to thereby obtain stained nucleated cells, so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma and subsequently
- (c) imaging said stained nucleated cells resultant of step (b) so as to obtain images of said stained nucleated cells; and subsequently
- (d) staining said stained nucleated cells resultant of step (b) by using fluorescent in situ hybridization (FISH)- to thereby obtain stained nucleated cells so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell, and subsequently
- (e) imaging said stained nucleated cells resultant of step (d); and subsequently
- (f) simultaneously viewing said images stained nucleated cells resultant of steps (bc) and (de), and:
 - (f) identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality, wherein presence of said morphological abnormality and said chromosomal abnormality in said single cell is indicative of a presence of a cancerous cell;
to thereby determine the presence or absence of cancerous cells within said stained nucleated cells, wherein said presence of said cancerous cells is indicative of a positive cancer diagnosis.

74-81. (Cancelled)